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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,102	03/10/2000	Erwin Si	03654.0255	4492

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ARNOLD & PORTER
IP DOCKETING DEPARTMENT; RM 1126(b)
555 12TH STREET, N.W.
WASHINGTON, DC 20004-1206

EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/523,102

Applicant(s)
Si et al.

Examiner
Sandra Saucier

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1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 23, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above, claim(s) 43-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/16/00 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 13 6) ☐ Other:

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DETAILED ACTION

Claims 1-66 are pending. Claims 1-42 are considered on the merits. Claims 43-66 are withdrawn from consideration as being drawn to a non-elected invention.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. as follows:

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The instantly claimed methods are directed to the topical administration to the eye of a composition comprising batimastat and a polymeric suspension agent.

US 6,378,526 [C] does not provide sufficient support under 35 USC 112 for the presently claimed invention as '526 does not disclose any topical administration of batimastat to the eye, but merely discloses a method of injecting agents, of which batimastat is one in an extensive list of known agents, into the eye.

US 6,378,526 even teaches away from topical administration of active agents to the eye (col. 3, l. 45-50). In short, there is no overlapping disclosure of the instantly claimed invention. Therefore, the date of filing of the instant specification, 3/10/2000 is considered the date of invention at this time for the application of prior art.

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Claim Rejections – 35 USC § 112

INDEFINITE

Claims 1, 2, 4-8, 10-16, 18-24, 26-34, 36-39, 41 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite using “a batimastat compound”. However, no definition of what constitutes “a batimastat compound” is found in the claim or the body of the specification. For example, how closely related does a compound have to be to fall within the limitation of “a batimastat compound”. Do salts and esters fall within this limitation? Would a compound which lacks the terminal methyl on the amine group be considered to fall within or outside of the phrase “a batimastat compound”? Would the related compound, marimastat be considered to be “a batimastat compound”? Please point to a definition in the specification of what comprises a batimastat compound as used in the claims.

Claim Rejections – 35 USC § 103

Claims 1-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,767,153 [A] and WO 97/41844 [AH1] or US 5,763,621 [AC2].

The claims are directed to a method of treating retinal neovascularization in an animal comprising topically administering a composition comprising 0.01-3% w/w batimastat and a polymeric suspension agent, particularly polycarbophil.

The references are relied upon as explained below.

US 5,767,153 discloses a composition comprising 0.3% batimastat and 1.15% polycarbophil useful for topical ophthalmic administration, example 7.

WO 97/41844 discloses that batimastat is an angiostatic agent and as such is effective in compositions for the treatment of diseases where neovascularization arises such as diabetic retinopathies, proliferative vitreoretinopathies and other diseases (page 1, second paragraph and page 5, table 1). Compositions comprising metalloproteinase inhibitors such as batimastat, which is a preferred angiostatic agent (page 19, l. 9) are in topical

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ophthalmic formulations (claim 20).

The compositions may be used to prevent retinal neovascularization (page 20, l. 11).

US 5,763,621 discloses that metalloproteinase inhibitors are useful in the prophylaxis or treatment of proliferative retinopathies. Batimastat (BB-94) is taught to belong to the class of hydroxamic acid metalloproteinase inhibitors (col. 1, ls. 20-30 and col. 2, l. 35).

The substitution of the composition of batimastat and polycarbophil disclosed in US 5,767,153 for the batimastat composition taught in the methods of WO 97/41844 or US 5,763,621 would have been obvious because batimastat is known to be useful to treat retinal neovascularization as taught in '844 or '621 and the formulation of batimastat with polycarbophil as a suspension agent is taught in '153 to be particularly advantageous in terms of delivering a sustained dosage of a sparingly water soluble active ingredient such as batimastat over time.

One of ordinary skill in the art would have been motivated at the time of invention to use a composition of batimastat and polycarbophil to treat retinal neovascularization in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground of rejection.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. **Status inquiries must be directed to the Customer**

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Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.

A handwritten signature in black ink, appearing to be 'Sandra Saucier', with a large, stylized initial 'S' and a horizontal line extending to the right.

Sandra Saucier
Primary Examiner
Art Unit 1651
February 25, 2003